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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Mark A. Reiley

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

03/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/658,507	Applicant(s) REILEY, MARK A.	
	Examiner CHRISTOPHER D. PRONE	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/5/07 4/25/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner would like to note that the advisory action mailed on 2/25/09 was sent in error and has been subsequently vacated. Per the interview of 3/10/09 a new action has been issued.

Response to Applicant's Remarks

Applicant's request for clarification of the rejection of the last Office action is persuasive and, therefore, the finality of the previous action has been vacated and the instant Office action is a supplemental action with corrected rejections to the claims and is final. The period for response has been reset to the mail date of the instant Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50, 51, 52, 54, 55, 57, 59, 62-67, 78, 83-85, and 88 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fitz (Re 36758) or Vitale (5683466).

With respect to claim 50, Fitz discloses a prosthesis for the replacement of at least a portion of the bone of a facet located on a mammalian vertebra comprising: a surface that articulates with another facet surface; a fixation portion that is configured for implantation in an interior bone space of said vertebra, said surface being connected to said fixation portion. See figures 3 and 4. Note prosthesis portion 50 and 40 with fixation portions 58, 60, and 48.

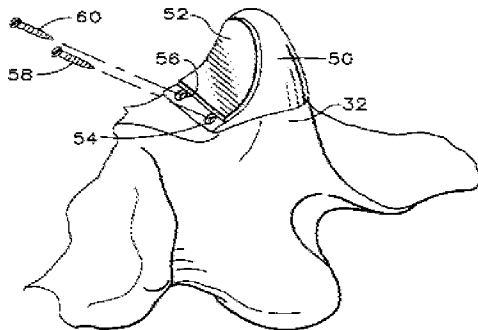


FIG. 3

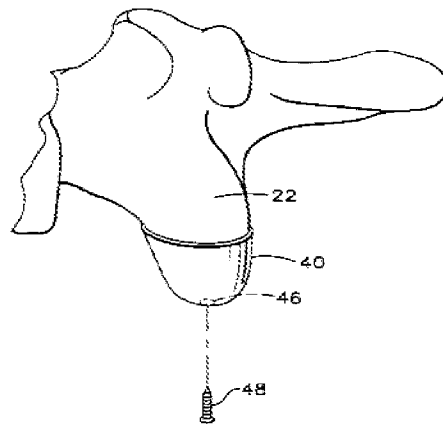


FIG. 4

Moreover, Vitale meets the limitations of claim 50 as Vitale discloses a prosthesis for the replacement of at least a portion of the articular surface of a bone comprising: a surface that articulates with another complimentary surface; a fixation portion that is configured for implantation in an interior bone space, said surface being connected to

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said fixation portion. See figure 2. Note prosthesis portion 26 and 20 with fixation portion 22.

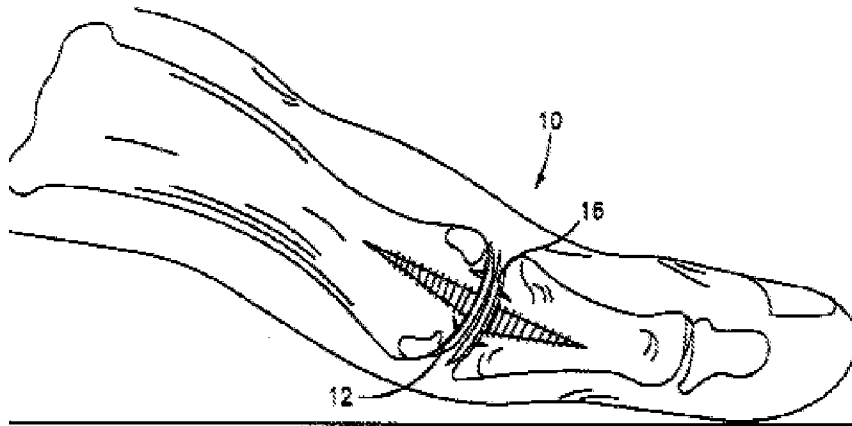


FIG. 2

Applicant has added language to the claims to further define the fixation portion.

“a fixation portion having a longitudinally-extending portion that is longer than a pedicle of the vertebra, said longitudinally-extending portion configured for implantation into an interior bone space of said vertebra, said surface being connected to said fixation portion”

Applicant's specification is silent as to any dimensional range for the fixation portion. It appears applicant is relying on the illustrated embodiments of the drawings for support for the newly added language. Applicant is relying on the drawings for support in establishing a length for the fixation element. Examiner argues that the length of the fixation elements as shown by Fitz is only illustrative to the same degree

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as applicant's reliance on the drawings. While applicant argues that Fitz fails to disclose a fixation element having a length that is longer than the pedicle, examiner contends that one with ordinary skill in the art would utilize an appropriate length fixation element that is required to provide proper fixation of the facet structure. A skilled surgeon would assess the bone and its surrounding tissues to determine what fixation element would be required to provide secure fixation of the implant. Such determination would not preclude the use of fixation elements that may be longer or shorter than that as illustrated in the drawings. The primary concerns for the surgeon is to provide adequate fixation without contributing unnecessary trauma to the bone and surrounding tissues.

Claim 51, see fixation portions 58, 60, and 48 adapted to be fitted into the interior bone space of a pedicle.

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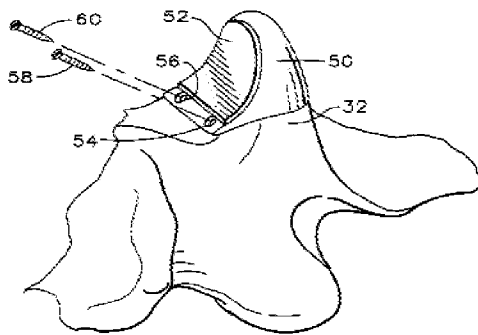


FIG. 3

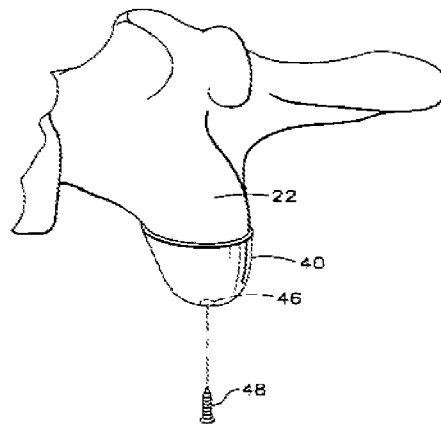


FIG. 4

Claim 52, see porous coating 44 and 66.

The adhesion of either the superior component 40 or the inferior component 50 or both to the underlying bone may be enhanced by applying a porous coating 44 and 66, respectively, to the inner surface of the superior component 40 or to the inner surface of the inferior component 54. In the preferred embodiment of this invention the porous material is of the same material as the component to which it is applied. There are many methods known to those skilled in the art for producing the porous coating. For example, the porous coating can be made up of small spherical particles that are attached to the interior surface by methods well known in the art. The porous coating will allow for bony ingrowth to occur and to firmly attach the component to the underlying bone.

s
P
d
u
40
u
45
c
c
c
40
b

Claim 54, see Fitz column 3, lines 20+.

Claim 55, the post of Fitz and Vitale are threaded, i.e. textured.

Claim 57, see rejection to claim 50 supra.

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Claim 59, see screw of Fitz and Vitale both having transverse width less than the transverse width of the pedicle.

Claim 62, see Fitz.

Claims 63-66, the placement of the device at the various levels of the vertebra does not distinguish over the device of Fitz or Vitale both, of which, are capable of placement in different vertebral levels of the spine.

Claim 67, the device of Fitz is removable connected to the fixation portion.

Claim 78 is similar to independent claim 50. The claim further defines a first and second facet surface each with affixing elements. Fitz and Vitale disclose first and second joint structures that articulate with each other. While the devices of Fitz and Vitale are specifically disclosed as being used independent of each other, they are capable of such function. The function of the device, as claimed, does not further define structural differences between the claimed device and that of the prior art. Therefore, since Fitz and Vitale each disclose the structure of the device as claimed and the device is capable of being used in the manner as claimed.

Claim 79, see Fitz column 3, lines 20+.

Claim 80, see fixation screw of Fitz or Vitale.

Claims 83-85, see rejection to corresponding claims supra.

Claim 88, see screw of Fitz or Vitale.

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Claims 50, 60, and 61 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Wall [4693722], Homsy, et al [4778472], Morgan [4917701] and Zang [5314486]

Wall, Homsy et al, Morgan and Zang disclose prostheses for the replacement of at least a portion of the articulating surfaces of cooperating bones of a joint. Each prosthesis comprises a surface that articulates with an adjacent joint surface; a fixation portion that is configured for implantation in an interior bone space and is connected to a fixation portion. Since each references discloses a prosthesis that includes a prosthesis body for fixation to an anatomical bone structure and an artificial joint structure carried by the prosthesis body these devices are capable of performing the function as broadly set forth in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52-59,68-77,81,82,86,87,89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitz (Re 36758) or Vitale (5683466) as applied to claim 50 above, and further in view of Davidson (5348026) or Bowman et al (4950270).

With respect to claims 52 and 53, Davidson and Bowman teach the concept for coating an osteo-screw with a coating of osteoinductive substance to reduce the

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tendency for stress concentration and promote new tissue attachment. To coat the screw of Fitz or Vitale with an osteoinductive material to reduce the likelihood of failure of the fixation of the implant would have been obvious to one with ordinary skill in the art from the teachings of Davidson or Bowman et al.

Claim 54, see column 2, lines 3+.

Each component of the device of this invention is made of a biocompatible material such as stainless steel, unalloyed titanium, or a titanium-aluminum alloy. The elongated side of the inferior component has a low coefficient of friction so that it offers minimal resistance to the movement of the superior component. This may be accomplished by coating the outer surface of the elongated side with either polished chrome or a friction reducing material such as a medical-grade high density polyethylene.

Claim 55, the screw post is textured.

Claim 56, the porous coating allows for bone fixation/ingrowth.

Claim 57, see screw elements 58, 60.

Claim 58 see rejection to claim 55 supra.

Claim 59, see posts of Fitz or Vitale which have a transverse width less than the width of the pedicle.

Claim 68 is essentially duplicative of independent claim 50. Minor differences in the manner of defining the device do not further distinguish the claimed device over that of Fitz or Vitale as applied to the claims supra.

Claims 69-77, see corresponding rejections to the claims supra.

Claims 81, 82, 86, and 87, see porous coating as taught by Davidson or Bowman.

Claim 89, see screw of Fitz or Vitale as modified by Davidson or Bowman et al.

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Response to Arguments

Applicant's response filed on 7/8/2008 has been considered. The Office action has been clarified to correct the various deficiencies.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hoffman et al 5,314,489 teaches porous coated implant.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is (571)272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
Art Unit 3738

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